Sounding the alarm for I.V. infiltration

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A PATIENT needed treatment with a skin graft after an infusion of phenytoin (Dilantin) infiltrated into his hand, permanently damaging nerves and tissue. His I.V. pump didn't sound an alarm during the infiltration.

Another patient, a dehydrated 18-month-old receiving a bolus of I.V. fluid, suffered an infiltration that made her arm swell from her hand to her elbow. The pump's I.V. pressure setting was set at a level considered potentially unsafe for children and infants. No alarm sounded during the infiltration. The child was transferred to a pediatric facility, where the injury was evaluated for surgery.

What went wrong?

The Food and Drug Administration receives many medical device problem reports about I.V. infiltration (the leakage of I.V. fluid into subcutaneous tissue). Many reports indicate that an I.V. pump malfunctioned because infiltration didn't set off the alarm. This reflects a common misconception: that downstream occlusion alarms can detect infiltration. The fact is infiltration doesn't normally produce enough pressure to trigger an alarm.

The case involving the infant spotlights another problem. Some I.V. pumps have pressure settings that can be adjusted for an adult or a pediatric patient. A pediatric patient can be harmed if she's getting an infusion at an adult pressure setting.

What precautions can you take?

- Before using an I.V. pump, check it to see if it's designed for pediatric or adult patients. Follow the manufacturer's recommendations for the appropriate patient population when setting the pressure for infusion and downstream occlusion

alarms. If you have questions about an I.V. pump, especially its infiltration detection capabilities, check with the manufacturer before using it. Or you can consult with your facility's biomedical department staff.

- When possible, use central lines to infuse hypertonic, vasoconstricting, corrosive, or other irritating solutions or medications, such as phenytoin, that can cause serious injury if they infiltrate into a peripheral site. Review your institution's policies about infusing these medications into peripheral veins.
- You can't rely on an I.V. pump's downstream occlusion detection to sound an alarm if an infiltration occurs, so follow your institution's policy for routinely assessing and documenting I.V. sites. Look for signs and symptoms of infiltration, such as swelling or cool skin, and ask the patient if the insertion site feels tender. Stop the infusion and remove the catheter if you suspect infiltration.
- Remind colleagues that downstream occlusion alarms aren't meant to detect infiltration.
- Instruct patients and family members to notify you or another nurse immediately if they experience any problems with their I.V. lines such as discomfort or swelling at the insertion site.
- If you suspect that a malfunction, serious injury, or death is device-related, follow your facility's policies and procedures for incident reporting. Notify the person at your facility who's responsible for reporting such problems or submit a voluntary adverse event report through MedWatch by calling 1-800-FDA-1088 or online at **www.fda.gov/medwatch.**

Downstream occlusion alarms don't normally detect infiltration because infiltration doesn't produce enough pressure to trigger an alarm.

Although you need to support the adverse **event–** reporting policy of your health care facility, you may voluntarily report a medical device that doesn't perform as intended by calling **MedWatch** at 1-800-FDA-1088 (fax: 1-800-FDA-0178). The opinions and **statements** in this report are those of the author and may not reflect the views of the Department of Health and Human Services. Beverly Albrecht **Gallauresi,** RN, BS, MPH, is a nurse-consultant at the Center for Devices and Radiological Health at the Food and Drug Administration in **Rockville,** Md., and coordinates Device *Safety*. Julia Marders is a nurse-consultant, also at the Center for Devices and Radiological Health.